Testimony of
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Committee on Energy and Commerce
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I. Introduction

Mr. Chairman and Members of the Committee, thank you for the invitation to appear before you today. It is my privilege to represent the U.S. Environmental Protection Agency during this discussion on the bittering agent denatonium benzoate. The bill under consideration, H.R.2567, would mandate the addition of this bittering agent to engine coolant or antifreeze that contains more than 10 percent ethylene glycol. At the present time, the Administration does not have a position on this bill.

II. Background

The Agency has collected limited information and performed some screening-level analyses on denatonium benzoate; however, we have not conducted a full risk assessment, nor is there available an extensive database of toxicity or environmental fate information on denatonium benzoate. Using the available information, the Agency has applied screening-level toxicity and environmental exposure estimation techniques that are often used in assessments of industrial chemicals prior to entry into commerce pursuant to the Toxic Substances Control Act (TSCA).

These analyses typically employ techniques where toxicity and exposure values are estimated from structurally similar compounds, using computer-based models or expert

judgment, where toxicity or environmental exposure values are predicted based on a chemical's structure. These analyses do not currently provide enough information for the Agency to conduct a thorough human health or environmental assessment on this chemical. As such, the Agency's analyses on denatonium benzoate should not be construed to be an Agency position on the health and safety of denatonium benzoate. There simply is not enough information available at this time to make such a finding. Nonetheless, I am pleased to share with the Committee the results of the Agency's screening-level analyses on the exposure and toxicity information that we have developed by employing the modeling techniques mentioned above.

III. Environmental Exposure

Based on the chemical's structure, denatonium benzoate is predicted to be water soluble; however, it is predicted that the chemical may readily move from water and adhere to soil or sediment. It is not predicted to bioaccumulate in living organisms. In addition, the chemical is not predicted to be volatile, so it would not be expected to move from water to the atmosphere. The chemical is predicted to be resistant to biodegradation. For example, if denatonium benzoate were to be released into a sanitary sewer system, it most likely would be removed in a sewage treatment plant through adsorption to sludge and not through appreciable biodegradation. If denatonium benzoate were released directly to surface waters, it would be expected to accumulate in sediments due to its predicted propensity to move from water and adhere to soil, and its resistance to biodegradation. The chemical would not be predicted to readily migrate to groundwater because of its propensity to adsorb to soil; however, with sandy soils, potential movement to groundwater would be greater than if applied to soil rich in organic matter.

IV. Human/Wildlife Exposure

Denatonium benzoate is one of the most bitter and bad tasting chemical substances known. Consequently, it is at times used as a minor ingredient in consumer products, such as denatured alcohol, to deter human ingestion. Because of human aversion to denatonium benzoate, oral exposure potential for humans is expected to be low. Other mammals are likely also averse to denatonium benzoate. If orally consumed, data on structurally similar chemicals leads us to believe it would not be readily absorbed in the gastrointestinal tract and not likely to be efficiently absorbed across the skin.

V. Human/Wildlife Toxicity

Our preliminary evaluation indicated there were no appreciable concerns identified for mutagenicity, carcinogenicity, or developmental toxicity from this chemical. Overall, given the limited data base, and the uncertainties thereby presented, it is predicted that there is low to moderate concern for toxicity to humans and mammalian wildlife and that the chemical is not likely to be highly toxic to birds.

VI. Aquatic Toxicity

Again, based on the models and the Agency's screening-level analyses, the compound is predicted to be moderately toxic to aquatic organisms and plants, with fish, aquatic invertebrates, and algae being least to most sensitive, respectively. The toxicity to fish, aquatic invertebrates, algae and aquatic plants in the water column is predicted to be reduced to the extent that soils or sediments are present in the water, again, because of the chemical's propensity to adhere to these materials.

V. Conclusion

Thank you for the opportunity to provide you with this information. While the information presented is limited and should not be construed as an Agency position on the health and safety of denatonium benzoate, I hope the information nonetheless is useful to the Committee as you consider this issue. I will be pleased to answer any questions.